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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/383,114	08/25/1999	JOHN A. ARCADI	35687/RW/H29	6120

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EXAMINER

GOLDBERG, JEROME D

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/02/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding. .

Office Action Summary

Application No.

09/383,114

Applicant(s)

ARCADI, JOHN A.

Examiner

Jerome D Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-8, 17-19, 25-27 and 30 is/are allowed.
- 6) ☒ Claim(s) 9-16, 20-24, 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 26, 2003 has been entered.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the arcadi reference (1986) and arcadi reference (1990), both of record. The arcadi reference teach applicant's compound for treating cancer in a saline solution. The references do not teach applicant's specific carriers set forth in the instant claims. Accordingly, one skilled in this art would find ample motivation from the prior art supra to make a pharmaceutical composition of the prior art rhodamine-123 anticancer agent with a reasonable expectation that said composition would be effective for treating cancer in the absence of a side – by- side comparison over the prior art pharmaceutical composition.

With regard to the intended application to treating human cancer patients, said intended application does not render the pharmaceutical composition ^{obvious} ~~unobvious~~. See

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In re Skoner '186 USPQ 80 (CCPA 1975); In re Kalm '154 USPQ 10 (CCPA 1967) and In re Halley 132 USPQ 16 (CCPA 1961) which are directly on point.

Claims 20, 22-24 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Bernal et al, reference of record as set forth in paper no. 14.

The Bernal et al. reference teaches Rhodamine -123 "exhibited anticarcinoma activity in mice with various exptl. Carcinomas..." (AB, lines 1 and 2). Accordingly, one skilled in this art would find ample motivation from the prior art supra to employ the prior art anti-carcinoma agent to treat carcinomas with a reasonable expectation that said anticarcinoma agent would be effective to combat said carcinoma. The Jones declaration, paper no. 23, is noted. The Jones declaration refers to the Bernal et al reference does not disclose that human life can be prolonged by treating victims of carcinoma with rhodamine-123, this is true but the instant claims are not directed to "prolonging human life". The declaration refers to exhibits B and C, these references are directed to in vitro data only while the instant reference is directed to in vivo ^{use} ~~data~~.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner J. D. Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday-Thursday 9:00 A.M - 3:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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305-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Goldberg/tgd
June 6, 2003



JEROME D. GOLDBERG
PRIMARY EXAMINER